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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,798	03/06/2002	Amanda S. Schilling	83202	6616

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,798

Applicant(s)

SCHILLING ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,10-16 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,10-16 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response filed 27 June 2006 to Office Action issued 27 March 2006 is acknowledged and entered.
2. Applicants' review of the prosecution history with respect to rejections under 35 U.S.C. §103(a) is greatly appreciated.

CLAIMS STATUS

3. Claims 1, 4-5, 7, 10-16 and 23 are pending.

Claim Rejections Under 35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4-5, 7, 10-16 and 23 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Clouston (U.S. Patent 3,617,178) in view of each of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al. (U. S. Patent 6,506, 803) for the reasons of record in the Office Action mailed 27 March 2006.

Claims recite a method to decontaminate a composition contaminated with biological spores via simultaneously or sequentially germinate and kill biological spores in said composition through treating said spores with a germinant comprising dipicolinic acid and calcium ions and a germicidal solution. Said germinant solution comprises 50-90 mM of each one of calcium ions and dipicolinic acid. The composition administered in said method also comprise a germicidal solution, a surfactant comprising at least one carbon chain of at least \geq six carbon members, a peroxide compound and an enzyme.

In response to the art rejections in Office Actions cited *supra*, applicants argue that the claimed invention is unobvious over the cited references (i.e., Clouston (U.S. Patent 3,617,178)

in view of each of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al (U. S. Patent 6,506, 803), “the reasoning behind” said “rejection was set forth in item 10 of a previous Office action mailed March 05, 2004 (Paper Number 20040225)” (i.e., rejection based on Baugh et al. (U.S. Patent 6,656,919) in view of Paidhungat et al. (Journal of Bacteriology, 2000, Volume 182, Pages 2513-2519), Baker et al (U. S. Patent 6,506, 803) and are further obvious over Clouston (U.S. Patent 3,617,178) in view of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al (U. S. Patent 6,506, 803). It is stated that the claimed invention is unobvious over the examiner-cited prior art references, because “in light of the nature of the art with which the invention is concerned, there has been an insufficient showing of teaching, suggestion, or motivation to combine the cited references so as to establish that the claimed invention would have been obvious.” Applicants further argue that there is “no showing that a person of ordinary skill in the art would have had a reasonable expectation of the success in the result of combining the teachings of the references.” Citing several excerpts from the examiner-cited references and case laws, applicants also argue that the “PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some *objective* teaching *in the prior art* or that *knowledge generally available* to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.”

Applicant’s above-cited arguments have been fully and carefully considered but are not persuasive because of the reasons of record and additional reasons discussed below.

- I. Applicants correctly note that the claims have been rejected over the prior art because the prior art appears to render the claims unpatentable. In traversing the 35 U.S.C. §103(a) rejection referred to *supra*, applicants argue that one skilled in the art would not know how to combine the teachings of cited prior art references in said rejection. If applicants are correct, then it would appear that one skilled in the art would not know how to practice the invention as claimed. The skill involved in combining the teachings of the cited prior art references to be the same skill that would be applied to practice applicants’ claimed invention. Applicants must reconcile how, on the one hand, one skilled in the art would not know how to combine the teachings of cited prior art

references, while on the other hand would know how to practice the invention as claimed, because:

- i. Applicants' claims are drawn to a method to decontaminate a composition contaminated with biological spores via simultaneously, or sequentially germinate and kill biological spores in said composition;
- ii. Clouston teaches the basic and general concept of a method to sequentially kill the bacterial spores by first germinating said spores, and subsequently kill said germinated spore preparation. Thus, in contrast to applicants' repeated assertions (e.g., see Remarks page 4, Line 26) Clouston gives an "objective" teaching for a method to sequentially germinate and skill germinated bacterial spores;
- iii. In regard to applicants' reference to the basis for rejection cited *supra* in "a previous Office Action mailed March 05, 2004", said rejection mailed 05 March 2004 stated, "Claims 1-16 are rejected under 35 U.S.C. § 103 (a) as obvious over Baugh et al. (U.S. Patent 6,656,919) in view of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al (U. S. Patent 6,506, 803)". In said rejection, again Baugh et al. reference presents the basic and general concept of simultaneously rendering the bacterial spores harmless or lifeless by subjecting them to germinant and germicidal solutions. Baugh et al. even present the alternate concept of sequentially germinating and killing the germinated spores, wherein the germinant solution comprises among other components, dipicolinic acid (i.e., DPA) and calcium.
- iv. Paidhungat et al, investigate a range of combinatorial concentrations (i.e., in range of <20 mM to 90 mM) of dipicolinic acid (i.e., DPA) and calcium cation (i.e., Ca^{2+}) to demonstrate that highest germination of bacterial spores occurs when the concentration of each component, i.e. Ca^{2+} and DPA each in the germinant was equimolar at 60 mM (Page 2517, Column 2, Lines 17-29 under Table 4 and Figure 4). Thus, in contrast to applicants' assertion, Paidhungat et al. have indeed demonstrated judicious selection and routine optimization to show that an equimolar concentration of 60 mM of each of the

two components in the germinant solution is required to achieve optimum (i.e., highest) germination. The range of concentrations are within the range of concentration (i.e., 10 mM to 150 mM or even applicants' claim of precise concentration of 50 mM-90mM (see Claim 4))) for each of the two components (i.e., calcium cations and dipicolinic acid) that are instantly claimed to be comprising the germinant solution. Thus, in contrast to applicants' assertion (See Remark Page 6, Lines 23-25) that Paidhungat et al. teach away from the instantly claimed invention, Paidhungat et al.'s teaching from Figure 4 and the relevant text read on the claimed invention because spore germination is maximum at the equimolar concentration of 60 mM of each of DPA and calcium cation, wherein said 60 mM concentration is within the range of 50mM-90 mM;

- v. Baker et al.'s composition and method teaches same step and a composition comprising same/similar ingredients as instantly claimed to kill the germinated spores or bacterial cells.
- vi. Thus, Clouston's generalized and basic concept of sequentially germinating and killing bacterial spores, or Baugh et al.'s generalized concept of simultaneously or sequentially germinating and killing bacterial spores, not the details of executing said concepts is executed according to the teachings from Paidhungat et al. who teach a method and a composition to germinate bacterial spores by treating said spores with a germinant solution comprising each of cationic calcium and DPA in the range of <20 mM to 90 mM and the second part of Clouston's/ Baugh et al.'s concept of subsequently killing said germinated spores (i.e., bacterial spores) by subjecting said germinated spores according to Baker et al., who teach a method and germicidal composition, wherein said germicidal composition comprises a surfactant, an enzyme and a buffer.

Thus, in contrast to applicants' repeated assertions that there is no "objective" teaching in the references (See e.g., Remarks Page 4, Lines 11 and 26), and further in contrast to applicants' assertion (see e.g., Remarks, Page2, Lines 14-15), both the suggestion and motivation are present in the prior art references, because the generalized concept of a method to simultaneously or sequentially germinate and kill bacterial spores is present in Clouston's/ Baugh et al.'s teachings,

Paidhungat et al. not only give the composition, but also the optimum concentration of a germinant solution to achieve maximum bacterial spore germination, and Baker et al's teachings provide a method and a composition to kill germinated bacterial spores/cells. Thus, again in contrast to applicants' assertion, the teachings from each of the prior art references not only make the claimed invention *prima facie* obvious to skilled artisan, the prior art teachings also provide said artisan with motivation to combine the teachings from the prior art references to successfully achieve the claimed invention, because claimed invention also employs the same method steps and composition as are present in the prior art teachings. Furthermore, the teachings of each one of the prior art were well known at the time of the claimed invention and were therefore available to a skilled artisan at the time of instantly claimed invention.

Thus, from the discussion presented *supra*, it is clear that the PTO has established a "*prima facie* case of obviousness" and that burden is satisfied by "showing some *objective* teaching *in the prior art* or that *knowledge generally available* to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references".

Although each of the Examiner-cited references by themselves do not teach every component as claimed in the claims under prosecution in the instant application, these references are not relied upon exclusively but in combination. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference which is the case in point as is taught from Clouston reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or describe Applicants' invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the invention was made.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 2-3, items 5-6 in Office Action mailed 28 March 2006 and for additional reasons discussed in item 8 *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

CONCLUSION

6. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


7. For the aforementioned reasons, no claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571)

272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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GROUP 1200

September 25, 2006